WO 2005/095390 PCT/EP2005/003332

17

## Claims

- 1. A coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier.
- 2. A coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier according to claim 1, wherein the carrier is selected from the group consisting of polyvinylpyrrolidone, silicium dioxide, mannitol, lactose, methylcellulose and cyclodextrin.
- 3. The coprecipitate according to claim 1, wherein it is the coprecipitate of amorphous rosiglitazone maleate with polyvinylpyrrolidone.
- 4. The coprecipitate according to claim 1, wherein it is the coprecipitate of amorphous rosiglitazone maleate with silicon dioxide.
- 5. The coprecipitate according to claim 1, wherein it is the coprecipitate of amorphous rosiglitazone maleate with mannitol.
- 6. The coprecipitate according to claim 1, wherein it is the coprecipitate of amorphous rosiglitazone maleate with lactose.
- 7. The coprecipitate according to claim 1, wherein it is the coprecipitate of amorphous rosiglitazone maleate with methylcellulose.
- 8. The coprecipitate according to claim 1, wherein it is the coprecipitate of amorphous rosiglitazone maleate with gamma-cyclodextrin.
- 9. A coprecipitate according to claims 1 to 8, wherein the ratio of amorphous rosiglitazone maleate to a pharmaceutically acceptable carrier ranges from 1:1 to 1:20.

WO 2005/095390

PCT/EP2005/003332

- 10. A coprecipitate according to claims 1 to 8, wherein the ratio of amorphous rosiglitazone maleate to a pharmaceutically acceptable carrier ranges from 1: 1 to 1: 4.
- 11.A process for the preparation of a coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier, which comprises the steps of:
  - a) dissolving rosiglitazone maleate in an organic solvent or in an aqueous solution of organic solvent,
  - b) adding pharmaceutically acceptable carrier,
  - c) spray-drying the obtained solution.
- 12. The process according to claim 11, wherein a pharmaceutically acceptable carrier is selected from the group consisting of polyvinylpyrrolidone, silicon dioxide, mannitol, lactose, methylcellulose and cyclodextrin.
- 13. The process according to claim 11, wherein an organic solvent is selected from the group consisting of ethanol and acetone.
- 14. The process according to claim 11, wherein the range of organic solvent to water is from about 9 : 1 to about 1 : 1 (V / V).
- 15. The process according to claims 11, wherein the range of organic solvent to water is from about 9:1 to about 7:3 (V/V)
- 16. A process for the preparation of a coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier, which comprises the steps of:
  - a) dissolving rosiglitazone (base) in an organic solvent
  - b) adding maleic acid and stirred the mixture to obtain a clear solution,
  - c) adding pharmaceutically acceptable carrier,

WO 2005/095390 PCT/EP2005/003332

19

- d) spray-drying the obtained solution.
- 17. A pharmaceutical composition comprising a coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier and other excipients.
- 18. A coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier according to claims 1 to 10, for use in the treatment and / or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.
- 19. The use of a coprecipitate of amorphous rosiglitazone maleate with a pharmaceutically acceptable carrier according to claims 1 to 10, for the manufacture of a medicament for the treatment and / or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.
- 20. A solid solution of rosiglitazone maleate with a pharmaceutically acceptable carrier.
- 21. A solid solution according to claim 20, wherein the pharmaceutically acceptable carrier is selected from polyethylene glycols between 4000 to 40.000 of average mol. weight.
- 22. A process for the preparation of a solid solution of rosiglitazone maleate with a pharmaceuticall acceptable carrier, which comprises the steps of:
  - a) melting rosilitazone maleate or optionally rosiglitazone and maleic acid with a pharmaceutically acceptable carrier to form a melt
  - b) cooling the obtained melted solution

WO 2005/095390 PCT/EP2005/003332

20

- 23. The process according to claim 22, wherein a pharmaceutically acceptable carrier is selected from polyethylene glycols between 4000 to 40.000 of average mol. weight.
- 24. A pharmaceutical composition comprising a solid solution of rosiglitazone maleate with a pharmaceutically acceptable carrier and other excipients.